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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/619,285	07/19/2000	Jeno Gyuris	MIV-109.01	2224

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ROPES & GRAY LLP
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EXAMINER

YU, MISOOK

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 07/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/619,285

Applicant(s)

GYURIS ET AL.

Examiner

MISOOK YU, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-34 and 49-91 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-34 and 49-91 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>20</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Claims 28-34, and 49-91 are pending and examined on merits.

Information Disclosure Statement

The information disclosure statement filed 4-25-2003 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance for the French document (AH), as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 103

Claims 28-34, and 49-91 remain rejected for reason of record under 35 U.S.C. 103(a) as being unpatentable over PCT/FR95/30759 (AB of IDS, Paper No. 14, publication date: 11/16/1995).

Applicant argues that the prior art does not teach or give motivation to insert heterologous peptide in the specific sites of serum albumin recited in the claims, the art define the insertion region by function, not by structure i.e., the wished-for insertion regions wit certain characteristics, as opposed to teaching a skilled artisan where these regions are located on serum albumin, and the prior art is nothing more than invitation to do more research, has no reasonable expectation of success without undue experimentation at arriving the specific regions recited in the claims. These arguments have been fully considered but found not persuasive because the prior art of record (PCT/FR95/30759) teaches that the crystal structure of serum albumin has been solved in 1992 by He and Carter (see page 6, the last para) indicating the art know which residues are exposed loops, thus teaching where the wished-for insertions is located structurally. The specifically recite residues 360-369 in instant base claim 28 is loop connecting h9 and h10 of Figure 1 of PCT/FR95/30759. Further, Carter and He (IDS AE filed on 6/05/2002, 1994, Advanced in Protein Chemistry 45, pages 153-203) MA 4n- ambiguously teaches that the detailed crystal structure had been known before the publication date of the art of record. The Office maintains that the knowledge in the art at the time the instant application was filed was sufficient for inserting heterologous

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peptide into the recited sites with reasonable expectation of success and for screening to see whether the inserted heterologous peptide is active or not. Since the specification does not show any unexpected result for the specific recited sites, the Office maintains that the claimed invention is obvious variants of the prior art.

Double Patenting

Claims 28-34, and 49-91 remain provisionally rejected for reason of record under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 28-33, and 54-104 of copending Application No. 09/768,183 because applicant has not filed terminal disclaimer.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu

July 25, 2003

Mary Mosher
MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1600
1600